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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/806,322 | 06/05/2001 | Thomas J. Bormann | 440446 | 6774 |

23548 7590 08/05/2002

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| EXAMINER | |
|---|---|
| MENON, KRISHNAN S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1723 | 8 |

DATE MAILED: 08/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MK-7

| Office Action Summary | Application No. 09/806,322 | Applicant(s) BORMANN ET AL. | |
|---|---|---|---|
| | Examiner Krishnan S Menon | Art Unit 1723 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The second page of the form 1449 from the information disclosure filed by the applicant was overlooked by the examiner as the page was stuck to the first page due to irradiation of the file. However, the references in the second page were reviewed by the examiner before the first office action was mailed. Applicant is hereby granted a new 3-month reduced statutory period, beginning from the date of mailing of this correspondence, to reply to this office action.

## DETAILED ACTION

### *Specification*

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. The abstract published in the international publication WO 00/20053, Para 57, will be used if a separate abstract is not submitted

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 recites the limitation "leukocyte containing plasma-rich fluid" in the first line. There is insufficient antecedent basis for this limitation in the claim. The examiner will consider this claim as dependent on claim 12 instead of claim for examining purpose.

### *Double Patenting*

Claims 3 and 20 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 2 be found allowable, claims 3 and 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 18 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 17. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 17 be found allowable, claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

## *Claim Rejections - 35 USC § 102*

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 10 is rejected under 35 U.S.C. 102(a) as being anticipated by Kraus (US 5,783,094). Kraus discloses a method for processing blood comprising passing plasma through a filter device comprising a filter having a leukocyte depletion medium and a membrane and collecting filtered plasma substantially free of leukocytes (example 24).

## *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 11-14, 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus (US 5,783,094) in view of Onodera (US 5,406,581).

Kraus (094) teaches a filter (abstract) for processing biological fluids such as blood comprising a housing (example 24) with porous fibrous leukocyte depletion medium with a second layer of membrane (col 3: 40-63), the leukocyte depletion medium allowing plasma to pass through while substantially depleting the leukocytes (example 24-26). Kraus discloses the first filter (pre-filter) as having two or more layers (examples) as in claim 5 and one membrane layer as in claim 7 of the instant application, the membranes having pore sizes from 2 to 20 microns as in claims 1, 17 and 19 of the instant application.

Kraus (094) does not elaborate on the housing and is silent on the inlet and outlet. Onodera (581) teaches a housing with inlet and outlet with the filter in between (abstract). It would be obvious to one of ordinary skill in the art at the time of invention that a filter needs a housing with

inlet and outlet for the fluids to pass through, and is a common engineering practice to provide such housings with inlets and outlets. One of ordinary skill in the art could also follow the teaching of Onodera (581) to provide such a housing to the Kraus filter to obtain an equivalent system that affords equivalent function as in claim 1 of the instant application.

Kraus (094) teaches a filter that filters the leukocytes from blood. However, Krause fails to teach a filter that filters RBC allowing only plasma to pass through. Onodera (581) teaches about membranes (col 4: 24-48) that remove all blood cells and allow only plasma to pass. It would be obvious to one of ordinary skill in the art at the time of invention to use Onodera teachings and add a membrane down-stream of the filter as taught by Kraus (094) to remove the red blood cells as well, as equivalent to the filter in claim 2 of the instant invention and providing equivalent results.

Kraus (094) fails to teach about processing the blood before filtering to supernatant layer comprising plasma and leukocytes, and sediment layer comprising red blood cells as in the claim 12 and 14 of the instant application. Onodera (581) teaches centrifugation to separate the blood to plasma rich and red blood cell rich parts (example 21). It would be obvious to one of ordinary skill in the art at the time of invention to use the Onodera (581) method of centrifuging the blood before filtration and then using an RBC filtration membrane as taught by Onodera (581) to separate plasma from blood in a method as taught by Kraus as an equivalent method affording equivalent results.

Kraus (094) fails to teach about red cell barriers as in claims 2, 11 and 14, melt blown filters as in claim 4, CWST of at least 90 as in claim 6, filter arranged substantially to prevent red blood cells through as in claim 8, and containers suitable for blood as in claim 9. Onodera (581) teaches a membrane and a method for filtering/removing red blood cells from fluids (col 4: 24-48), melt blown media (col 15: 54-63), CWST of about 90 (col 17: 45-68) and bladders upstream and down stream of filters (example 21). It would be obvious to one of ordinary skill in the art at the time of

invention to use the teachings of Onodera (581) with the teachings of Kraus (094) to have a method of separating blood or similar fluids to deplete all the blood cells and obtain pure plasma using melt blown filters, membranes and containers suitable for blood, and to have a filter and filter system, and one could chose such a system as equivalent and providing same results to the present application.

## *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hagihara (US 5,008,012) and Deniega (US5,762,791) describe plasma separation with membranes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Application/Control Number: 09/806,322
Art Unit: 1723

Krishnan S. Menon
Patent Examiner
July 18, 2002

W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700